

CHARGE: 502 (f) (1)—the labeling of the articles failed to bear adequate directions for use in the treatment of the diseases for which the articles were recommended orally by the defendant, namely, (Formula No. 1 and Formula No. 556) ulcers, (Formula No. 3 and cold salve) arthritis, and (Formula No. 4) diabetes.

PLEA: Not guilty.

DISPOSITION: The case was tried before the court without a jury on 6-11-56.

On 6-20-56, after consideration of the evidence and briefs of counsel, the court handed down its findings of fact, conclusions of law, and verdict of guilty, as reported in 144 F. Supp. 229. On 6-27-56, the court fined the defendant \$2,000, sentenced him to serve 1 year and 1 day in prison, and placed him on probation for a period of 5 years, to begin upon his release from prison.

5144. Tryptacin tablets. (F. D. C. No. 35585. S. Nos. 19-876 L, 39-562 L, 43-165 L, 48-106 L, 64-364 L, 72-361 L.)

INDICTMENT RETURNED: 3-1-55, N. Dist. Ohio, against Rhodes Pharmacal Co., Inc., Cleveland, Ohio, J. Sanford Rose, president, and Jerome H. Rose, vice president and treasurer, of the corporation.

SHIPPED: Between 9-18-52 and 9-29-53, from Ohio to Minnesota, West Virginia, Louisiana, Washington, and California.

LABEL IN PART: (Btl.) "Tryptacin RHODES * * * Each tablet contains Aluminum Hydroxide Gel (Dried), Magnesium Trisilicate, Magnesium Oxide, Polyamine Methylene Resin, Ethyl p-Aminobenzoate (Benzocain) and water soluble Chlorophyllins in a special demulcent base."

RESULTS OF INVESTIGATION: The article was represented in its advertising for use in the treatment of stomach ulcers.

CHARGE: 502 (f) (1)—the labeling of the article failed to bear adequate directions for use since its labeling failed to state all of the conditions and diseases for which the article was intended to be used and was offered to the public in its advertising, and since the labeling of the article failed also to state the dosage and frequency and duration of administration for the treatment and prevention of such conditions and diseases.

PLEA: Guilty—by corporation; nolo contendere by individuals.

DISPOSITION: 6-29-56. Corporation fined \$5,500; individuals placed on probation for 3 years.

5145. Dextro-amphetamine sulfate tablets. (F. D. C. No. 39204. S. Nos. 18-962 M, 19-483/4 M, 19-486/7 M, 23-854 M, 30-682 M, 31-060 M.)

INFORMATION FILED: 12-11-56, S. Dist. Ohio, against Ace Tablet Co., a partnership, Steubenville, Ohio, and Rinaldo D. Tarquinio, partner.

SHIPPED: Between 10-12-55 and 3-17-56, from Ohio to Arizona, Tennessee, and Kentucky.

LABEL IN PART: (Btl.) "Tablets Dextro Amphetamine Sulfate 5 Mg. Caution: Federal law prohibits dispensing without a prescription."

RESULTS OF INVESTIGATION: The tablets were shipped to persons who were not authorized to receive them.

CHARGE: 502 (f) (1)—the labeling of the article failed to bear adequate directions for use.

PLEA: Guilty.